



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
)	Before Examiner
Cefali et al.)	
)	Pili Asabi Hawes
U.S. Serial No 08/962,421)	
)	
Filed: October 31, 1997)	Group Art Unit 1615
)	
INTERMEDIATE RELEASE NICOTINIC ACID)	
COMPOSITIONS FOR TREATING HYPER-)	
LIPIDEMIA WHICH EXHIBIT AN IN VIVO)	
STAIR-STEPPED ABSORPTION CURVE)	

Honorable Commissioner of Patents and Trademarks
Washington, DC 20231

Sir:

DECLARATION UNDER 37 CFR 1.132

I, Eugenio A. Cefali hereby declare that:

1. I am employed by Kos Pharmaceuticals, Inc. at its 2 Oakwood Blvd, Suite 100, Hollywood, Florida office (insert address).

2. I am a co-inventor of U.S. Patent Application No. 08/962,421, filed October 31, 1997.

3. I was awarded a Bachelor of Science in Pharmacy from St. John's University; A Pharm.D. from Virginia Commonwealth University; I was also awarded a Ph.D. in Pharmaceutics by Virginia Commonwealth University.

4. I joined Kos Pharmaceuticals, Inc. in 1994 and I have worked in Biopharmaceutics and Pharmacokinetics for the research and development of multiple compounds including estradiol, diltiazem, nicotinic acid, and several new chemical entities (describe projects in general terms).

5. I am a named inventor on seven (7) United States patents including U.S. patent number 6,406,715.

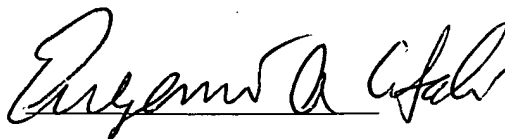
6. The preferred embodiment of the invention described and claimed in the patent application relates to a method of treating hyperlipidemia wherein an intermediate release nicotinic acid formulation is given in a once per day dosage form which exhibits an *in-vitro* stair-stepped absorption profile when a convoluted plasma curve for nicotinic acid release from said formulation is deconvoluted using the Wagner-Nelson method, wherein the stair-stepped absorption profile is generally characterized by three phases in which (1) up to 19% of the nicotinic acid dose is absorbed between about 1 and about 4 hours following ingestion, (2) between about 78% and about 100% of the nicotinic acid is absorbed between about 5 and about 9 hours following ingestion, and (3) between about 86% and about 100% of the nicotinic acid is absorbed by about 9 hours following ingestion.

7. I have read the Office Action mailed December 30, 2005 from the United States Patent and Trademark Office, and I have reviewed the references cited by the Examiner in that Office Action, particularly U.S. Patent No. 6,406,715 (Cefali).

8. The invention claimed in the current pending application was derived and based on parent application 08/814,974 filed March 6, 1997, now U.S. patent number 6,129,930, also the parent application of the cited reference, U.S. patent number 6,406,715 (Cefali).

9. The work described in the patent application was derived from the same work that formed the basis for the invention set forth in the cited reference, U.S. Patent No. 6,406,715 (Cefali), filed on even date.

I hereby declare that all statements made herein are of my own knowledge, are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Eugenio A. Cefali

March 3, 2006

Date